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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,859	08/16/2000	Leonard S. Girsh	5163*3	2441

23557 7590 07/30/2002

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	14

DATE MAILED: 07/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N . 09/639,859	Applicant(s) GIRSH, LEONARD S.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this c mmunication appears n the cover sheet with th corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,15-18 and 23-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-11,15-18 and 23-95* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In the preliminary amendments filed October 30, 2000, December 19, 2000, and September 27, 2001, claims 16-22 and 23-88 have been added, and claim 12 has been cancelled. In applicants' response to the restriction requirement filed June 24, 2002 (Paper No. 12), claims 2, 13-14 and 19-22 have been cancelled, and claims 89-95 have been added; In the supplemental amendment filed June 26, 2002 (Paper No. 13), claims 94 and 95 have been amended, thus claims 1, 3-11, 15-18 and 23-95 are pending. Applicants' election of Group II, claims 4, 6-10, 15 and 23-88 (Paper No. 12) without traverse is acknowledged, however, the claims were found to contain more distinct inventions, thus the pending claims are restricted in this Office Action.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

   I. Claims 1, 3 and 16-18, drawn to a composition, comprising amino acid, essential lipid, antioxidant lipid, and mucosaccharide or collagen; and a method of treating a damaged tissue by administering the composition, classified in class 436, subclasses 89 and 71, and class 514, subclass 54.

   II. Claims 4-10 and 15, drawn to a composition, comprising amino acid in which the molar ratio of amino acids corresponds to the molar ratio of amino components in medicament, essential lipid, and optionally addition of chondroitin sulfate and eicosopentanoic acid; and a method of treating a damaged tissue by administering the composition, classified in class 436, subclasses 89 and 71.

III. Claim 11, drawn to a composition, comprising amino acid, lipid, mono- or di-saccharide, vitamin, mineral and antioxidant, classified in class 436, subclasses 89 and 71, and class 514, subclass 54.

IV. Claims 23-33, 36-44 and 84-88, drawn to a method of treating an organ disease, organ damage, tissue disease or tissue damage, comprising administering the composition, comprising a combination of cellular, cell membrane and extracellular matrix derived ingredient to a human, classified in class 424, subclass 520.

Should Group III be elected, applicant is required to elect one condition or disorder from claim 37, 38, 43, 44, 86, 87 or 88. This is not species election. Each disorder is considered patentably distinct because each disorder has different cause, can use different drug for the treatment, and has different outcome in the treatment.

V. Claims 34 and 35, drawn to a method of stimulating cell growth, comprising administering the composition, comprising a combination of cellular, cell membrane and extracellular matrix derived ingredient to a human, classified in class 424, subclass 520.

VI. Claims 45-83 and 89-95, drawn to a therapeutic composition, comprising extracellular matrix compounds, polar surface active lipids and amino acids, wherein the components can be derived from cellular or tissue sources, or synthetically produced, classified in class 436, subclasses 89 and 71, and class 424, subclass 520.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Inventions I, II, III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the different inventions are drawn to different compositions, which have different components, e.g., the composition of Invention I contains mucosaccharide or collagen, which is not in the composition of Invention II, the composition of Invention III contains mono- or disaccharide, vitamin and mineral, which are not in the compositions of Inventions I and II; the composition of Invention VI contains extracellular matrix compounds such as glycoproteins, and polar surface active lipids such as phospholipids, which can be derived form cellular or tissue and are materially different from the components of Inventions I, II and III.

The product of Invention I is distinct from the methods of Inventions II, IV and V because the product of Invention I can be neither made by nor used in the methods of II, IV and V.

The product of Invention II is distinct from the methods of Inventions I, IV and V because the product of Invention I can be neither made by nor used in the methods of I, IV and V.

The product of Invention III is distinct from the methods of Inventions I, II, IV and V because the product of Invention I can be neither made by nor used in the methods of I, II, IV and V.

The product of Invention VI is distinct from the methods of Inventions I and II because the product of Invention VI can be neither made by nor used in the methods of I and II.

The product of Invention VI and the methods of Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions IV and V are alternative processes of use of the product of Invention VI.

The methods of Inventions I, II, IV and V are patentably distinct each from the other because they have different method steps, utilize different materials and produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

A telephone call was made to Frank Eisenschenk on July 29, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

***
July 29, 2002

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600